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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

Applicant(s)

08/950,963

Examiner

Art Unit

Ardin Marschel

1631

Drewes et al.

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE ____3____ MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). - Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). 2b) X This action is non-final. 2a) This action is **FINAL**. 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte QuaW835 C.D. 11; 453 O.G. 213. Disposition of Claims is/are pending in the applica 4) X Claim(s) 1-50 4a) Of the above, claim(s) 13-17 and 35 is/are withdrawn from considera 5) Claim(s) is/are allowed. 6) X Claim(s) 1-12, 18-34, and 36-50 is/are rejected. 7): Claim(s) _____ are subject to restriction and/or election requirem 8) X Claims <u>1-50</u> Application Papers 9) The specification is objected to by the Examiner. 10) The drawing(s) filed on ______ is/are objected to by the Examiner. 11) The proposed drawing correction filed on ______ is: a pproved b) disapproved. 12). The oath or declaration is objected to by the Examiner. Priority under 35 U.S.C. § 119 13): Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d). a) All b) Some* c) None of: 1. Certified copies of the priority documents have been received. 2. [] Certified copies of the priority documents have been received in Application No. 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). *See the attached detailed Office action for a list of the certified copies not received. 14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e). Attachment(s) 18) Interview Summary (PTO-413) Paper No(s) ___ 15) X Notice of References Cited (PTO-892) 16) X Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) Notice of Informal Patent Application (PTO-152) 17) X. Information Disclosure Statement(s) (PTO-1449) 20) Other

Serial No. 08/950,963 - 2 - Art Unit: 1631

The art unit designated for this application has changed.

The art unit designated for this application has changed Applicant(s) are hereby informed that future correspondence should be directed to Art Unit 1631.

Applicants' arguments, filed 7/2/01, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Applicant is hereby notified that the required timing for the correction of drawings has changed. See the last 6 lines on the sheet which is attached entitled "Attachment for PTO-948 (Rev. 03/01 or earlier)". Due to the above notification Applicant is required to submit drawing corrections within the time period set for responding to this Office action. Failure to respond to this requirement may result in abandonment of the instant application or a notice of a failure to fully respond to this Office action.

Claim 9 is rejected, as discussed below, under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Since optical properties are instantly cited in claims it is unclear whether the "absorbent material" in claim 9 is meant to

- 3 -Serial No. 08/950,963 Art Unit: 1631 be light absorbent or liquid absorbent. Clarification via clearer claim wording is requested. The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action: A person shall be entitled to a patent unless --(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States. Claims 18, 19, and 23 are rejected under 35 U.S.C. § 102(b) as being clearly anticipated by Brecht et al. [Anal. Chim. Acta. 311:289(1995)]. This rejection is reiterated and maintained from the previous office action, mailed 4/4/01, as not being specifically argued and is still deemed proper. It is noted that the reference clearly defines the construction of an optical device with layers as instantly claimed and utilized with sample laminar flow. The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action: A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103(a).

Claims 1, 2, 7, 9, 18-26, and 36 are rejected under 35 U.S.C. \S 103(a) as being unpatentable over Oberhardt (P/N 4,849,340).

The various Figures in Oberhardt depict a variety of devices wherein channels, layers, and reaction chambers or volumes are shown as well as being placed on a support. Both single channel devices such as shown in Figures 2, 4, 5, 8, 15, etc. and multiple channel devices such as shown in Figures 62-65, 71, and 72 are described thereby in the reference. A condition for flow in the devices being laminar flow is described in column 15, lines 7-13, and in column 28, lines 35-55. Optical methods of measurement in the reference are described as preferred in column 10, lines 58-66. In column 10, line 67, through column 12, line 29, a wide variety of light paths for detection is described including waveguide practice as well as light measurement via reflection practice and/or absorbance which thus defines an antireflective layer as required in instant claim 7. See, for example, the optically active reflecting layers as described in column 11, lines 6-17, which thus are present in the devices of

the reference. The presence of a porous layer in the device is described in column 27, lines 41-55. The presence of attachment layering with an inherent analyte binding agent layer is described for antibody type reactions in column 29, line 39, through column 30, line 27. It is also noted that the concept of utilizing the device with "any of the many assays that may be performed using reaction slides" is set forth in column 14, lines 30-35.

Thus, it would have been obvious to someone of ordinary skill in the art at the time of the instant invention to optionally construct and utilize a device with laminar flow through various layer selections because Oberhardt describes a wide variety of optically active layers as well as supports, channels, analyte attachment layers, etc. as outlined above which are selectable given the various sections directed to these practices in Oberhardt.

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. Miller v. Eagle Mfg. Co., 151 U.S. 186 (1894); In re Ockert, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer <u>cannot</u> overcome a double patenting rejection based upon 35 U.S.C. 101.

- 6 -Art Unit: 1631 Serial No. 08/950,963 Claims 1-12, 18-34, and 36-50 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-12, 18-34, and 36-50 of copending application Serial No. 09/675,518. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented. The non-statutory double patenting rejection, whether of the obviousness-type or non-obviousness-type, is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent. In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); and In re Goodman, 29 USPQ2d 2010 (Fed. Cir. 1993). A timely filed terminal disclaimer in compliance with 37 CFR 1.321(b) and (c) may be used to overcome an actual or provisional rejection based on a non-statutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.78(d). Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b). Claims 1-12, 18-34, and 36-38 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-12, 18-34, and 36-38 of copending application Serial No. 09/675,518. Although the conflicting claims are not identical, they are not patentably distinct from each other because clarifying amendments have been made to the above listed instant claims and may be interpreted as being obvious variations due to said amendments.

- 7 -Art Unit: 1631 Serial No. 08/950,963 This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented. Two Patents to Oberhardt (P/Ns: 5,658,723 and 6,197,494) are cited on the enclosed PTO Form 892 as being of interest as being cumulative to the above Oberhardt based rejection described above. No claim is allowed. Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703)308-4242 or (703)305-3014. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ardin Marschel, Ph.D., whose telephone number is (703)308-3894. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (703)308-4028. Any inquiry of a general nature or relating to the status of this application should be directed to Patent Analyst, Tina Plunkett, whose telephone number is (703)305-3524 or to the Technical Center receptionist whose telephone number is (703) 308-0196. September 28, 2001 PRIMARY EXAMINER